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# NOTICE OF ALLOWANCE AND FEE(S) DUE

20995 7590 12/03/2009

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

| EXAMINER | |
|---|---|
| KOSSON, ROSANNE | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 12/03/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/586,894 | 07/21/2006 | Francis Sean Moolman | ADADA4.001APC | 5369 |

TITLE OF INVENTION: STABILIZATION OF ENZYMES IN AN EMULSION BY CROSS-LINKING

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | NO | $1510 | $300 | $0 | $1810 | 03/03/2010 |

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

**HOW TO REPLY TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**



PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

# PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail** **Mail Stop ISSUE FEE**
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**P.O. Box 1450**
**Alexandria, Virginia 22313-1450**
**or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20995 7590 12/03/2009

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

| |
|---|
| (Depositor's name) |
| (Signature) |
| (Date) |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|---|---|---|
| KOSSON, ROSANNE | 1652 | 435-001100 |

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1_____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2_____ 3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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| EXAMINER | |
|---|---|
| KOSSON, ROSANNE | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

DATE MAILED: 12/03/2009

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 427 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 427 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.



PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

| Notice of Allowability | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/586,894 | MOOLMAN ET AL. | |
| | Examiner | Art Unit | |
| | Rosanne Kosson | 1652 | |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--***

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *9/29/09*.

2. ☒ The allowed claim(s) is/are *1-8,11,13-19,30 and 31*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   **Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative, Mr. Raymond Smith, on November 13, 2009.

The application has been amended as follows. The claims are amended as follows. Claims 3 and 18 have been rejoined.

1. (currently amended) A process for producing enzyme particles comprising:

(a) providing an emulsion of droplets of a first liquid phase dispersed in a second liquid phase, with the one liquid phase being a hydrophilic phase and the other liquid phase being a hydrophobic phase which is immiscible with the hydrophilic phase, and with enzyme molecules being located at or within interfacial boundaries of the droplets and the second liquid phase;

~~adding a cross-linking agent to the hydrophilic phase and/or to the hydrophobic phase and/or to the emulsion,~~

(b) adding a temporary protectant to the hydrophilic phase and/or to the hydrophobic phase and/or to the emulsion, wherein the temporary protectant occupies active sites of the enzyme, thereby inhibiting occupation of the active sites by a cross-linking agent or reaction of a cross-linking agent with the active sites;

(c) adding a cross-linking agent to the hydrophilic phase and/or to the hydrophobic phase and/or to the emulsion;

(d) cross-linking, by means of the cross-linking agent, the enzyme molecules of the respective droplets~~, wherein the temporary protectant occupies active sites of the enzyme during the cross-linking, thereby inhibiting occupation of, or reaction with, the active sites by the cross-linking agent, with individual stabilized enzyme particles in which the enzymes molecules are immobilized with a majority of active sites of the enzyme molecules being orientated either towards the lumens of the particles or outwardly therefrom being formed from individual droplets~~; and

(e) recovering the individual enzyme particles from the second liquid phase.

2. (previously presented) The process according to claim 1, wherein the individual particles have openings so that the liquid phases can pass in or out of the particles.

3. (~~withdrawn~~ original) The process according to claim 1, wherein individual particles are liquid impervious.

4. (currently amended) The process according to claim 1, further comprising adding to the hydrophilic phase and/or to the hydrophobic phase and/or to the emulsion, a modifier for modifying the hydrophobicity and/or charge of the enzyme, wherein the modifier is selected from the group consisting of ~~an amino acid, a protein and a long chain hydrocarbon aldehyde~~.
(i) a precipitator for precipitating the enzyme onto the emulsion interfaces, (ii) an additive for modifying the pH, ionic strength, viscosity, magnetic properties, agglomeration tendency and/or zeta potential of the emulsion and/or the enzyme particles and (iii) a surfactant.

5. (previously presented) The process according to claim 1, wherein the enzyme is a lipase.

6. (previously presented) The process according to claim 5, wherein the lipase is selected from the group consisting of *Pseudomonas cepacia* lipase, *Pseudomonas fluorescens* lipase, *Pseudomonas alcaligenes* lipase, *Candida rugosa* lipase, *Candida antarctica* lipase A, *Candida antarctica* lipase B, *Candida utilis* lipase, *Thermomyces lanuginosus* lipase, *Rhizomucor miehei* lipase, *Aspergillus niger* lipase, *Aspergillus oryzae* lipase, *Penicillium* sp. lipase, *Mucor javanicus* lipase, *Mucor miehei* lipase, *Rhizopus arrhizus* lipase, *Rhizopus delemer* lipase, *Rhizopus japonicus* lipase, *Rhizopus niveus* lipase, and Porcine Pancreatic lipase.

7. (previously presented) The process according to Claim 5, wherein the provision of the emulsion is effected by dissolving the enzyme in the hydrophilic or water (W) phase and forming the emulsion by mixing the enzyme containing hydrophilic phase with the hydrophobic or oil (O) phase.

8. (previously presented) The process according to claim 7, further comprising selectively precipitating the enzyme at the interface when the emulsion is an oil/water (O/W) emulsion in which hydrophobic phase droplets are dispersed in a continuous hydrophilic phase, or within the droplet volume, when the emulsion is a water/oil (W/O) emulsion in which hydrophilic phase droplets are dispersed in a continuous hydrophobic phase.

9. (canceled)

10. (canceled)

11. (previously presented) The process according to claim 7, further comprising adding an amino acid to the emulsion to inhibit agglomeration of the individual enzyme particles.

12. (canceled)

13. (previously presented) The process according to claim 7, further comprising extracting the first liquid phase from the enzyme particles.

14. (previously presented) The process according to claim 7, wherein the hydrophilic phase comprises water.

15. (previously presented) The process according to claim 7, wherein the hydrophilic phase comprises a polyethylene glycol.

16. (previously presented) The process according Claim 7, wherein the hydrophobic phase comprises an oil, a hydrocarbon, an ether, or an ester.

17. (currently amended) The process according claim 7, wherein the emulsion is a W/O emulsion in which hydrophilic phase droplets are dispersed in a continuous hydrophobic phase, with a second enzyme, a cofactor and/or a reaction mediator ~~being present~~ in the hydrophilic phase.

18. (~~withdrawn~~ currently amended) The process according to Claim 5, wherein a triglyceride, which is hydrolysable by lipase, is used as the hydrophobic phase in [[, with]] an O/W emulsion~~,~~ ~~in which hydrophobic phase droplets are dispersed in a continuous hydrophilic phase, being formed and with the dispersed hydrophobic phase contained within the cross-linked particles~~

~~being~~ and wherein the triglyceride is hydrolyzed by the lipase during and after the cross-linking reaction.

19. (previously presented) The process according to claim 7, wherein said process comprises, prior to cross-linking, (1) the formation of an initial emulsion, in which hydrophobic phase droplets are dispersed in a continuous hydrophilic phase, (2) centrifugation of the emulsion and separation of a concentrated emulsion from a dilute hydrophilic phase, to increase lipase purity and (3) the inversion of the emulsion to form a n emulsion in which hydrophilic phase droplets are dispersed in a continuous hydrophobic phase, by the addition of a surfactant with a lower hydrophilic-lipophilic balance (HLB) value.

20 – 29. (canceled)

30. (previously presented) The process according to Claim 14, wherein the hydrophilic phase further comprises a buffer in the water.

31. (previously presented) The process according to Claim 15, wherein the hydrophilic phase further comprises water admixed with the polyethylene glycol.

The following is an examiner's statement of reasons for allowance. The prior art does not teach or suggest the claimed method. As previously discussed, Goldberg et al. (US 4,671,954) disclose a method of making a controlled-release drug delivery vehicle that is a W/O (water-in-oil) emulsion comprising porous particles. The composition is made by making an aqueous solution of a protein, such as an enzyme, and dispersing the water phase in the oil phase with the aid of a modifier, polyglutamic acid. Any suitable protein or polypeptide, such as

an enzyme, may be used in this method. The polyglutamic acid modifies (reduces) the hydrophobicity and increases the hydrophilicity and the surface charge of the particles. Increased surface charge, with each particle having the same negative surface charge, reduces the aggregation of the particles. The hydrophilic phase comprises water mixed with, i.a., polyethylene glycol, a dispersion-stabilizing polymer, in the form of a block copolymer of polyethylene glycol and polypropylene glycol. The hydrophilic/aqueous phase may comprise additional molecules, polypeptides or macromolecules. Thus, the aqueous phase may comprise a second enzyme. The oil phase can be a hydrocarbon, such as toluene. This method includes the step of cross-linking the protein molecules in the microspheres with an agent such as glutaraldehyde. See col. 2, line 20, to col. 3, line 54; col. 4, lines 4-33; col. 5, lines 1-27; col. 11, lines 13-25 and col. 31, lines 17-35. The enzyme particles are recovered from the second liquid phase (see col. 6, lines 24-25). The first liquid phase (the aqueous phase) is extracted by drying the particles (see Examples 1, 21 and 25 in cols. 6, 15 and 16). The specification discloses that the step of extracting the aqueous phase is carried out in one of several ways, such as drying (see p. 5, last paragraph). But the prior art, including Goldberg et al. does not disclose that, before the cross-linking reaction, the enzyme is contacted with a "temporary protectant," i.e., a reversible catalytic site blocker or inhibitor, to protect the catalytic site during the cross-linking reaction.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Mon., Thurs., Fri., 8:30-6:00, Tues., 8:30-2:00, Wed. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652
rk/2009-11-23

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656